SEP 2 2 2003

TOMEN

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K031604.

807.92 (a)(1): Name: Tomen America, Inc.
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New York, NY 10019
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Contact: Mr. Shuhei Kato

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name: GlycoMark™

Common Name: 1,5-anhydroglucitol (15AG) Assay

Classification: Assay, Glycosylated Hemoglobin; 21 CFR 864.7470

807.92 (a)(3): Identification of the legally marketed predicate device

GlycoMark™ is substantially equivalent to existing A1C assays, namely the Tina-Quant A1C Assay, K934070 (Roche Diagnostics Corporation, Indianapolis, IN). Both assay systems are indicated for use by people with diabetes to monitor glycemic control.

807.92 (a)(4): Device Description

The GlycoMark™ reagents provide for a fully automated enzymatic test for 15AG. The assay requires the two-reagent boxed set (Reagent 1 and Reagent 2) and the 15AG standard (purchased separately). A two-level control set ("Low" and "High") is also available separately.

807.92 (a)(5): Intended Use

The GlycoMark™ test provides quantitative measurement of 1,5-anhydroglucitol (15AG) in serum or plasma. The test is for professional use, and is indicated for the intermediate term monitoring of glycemic control in people with diabetes.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

Similarities / Differences Between GlycoMark™ and A1C Assays

CHARACTERISTIC	GlycoMark™	Tina-Quant A1C K934070
Intended Use	Quantitative measurement of 15AG in serum or plasma	Quantitative measurement of the percent of glycated hemoglobin in whole blood
Indications for Use	Indicated for the intermediate term monitoring of glycemic control in people with diabetes	Used in the management and treatment of diabetes, for monitoring long term glycemic control
Risk to Patient	Not a critical analyte - reflects glucose monitoring over time	Not a critical analyte - reflects glucose monitoring over time
Sample	Serum or plasma	Whole blood
Sample Preparation	Standard processing for serum or plasma	Prepare hemolysate with hemolyzing reagent
Calibration	Parameters and calibration factors provided by instrumentation company	Parameters and calibration factors provided by instrumentation company
Methodology	Colorimetric assay; sample plus the addition of Reagent 1 (pretreatment) and Reagent 2 (color reagent)	Turbidimetric inhibition immunoassay for hemolyzed whole blood
Detection Method/ Throughput	System adapted for high-throughput, laboratory analyzers, e.g., Hitachi 917	System adapted for high-throughput, laboratory analyzers, e.g., Hitachi 917
Testing Environment	Professional use	Professional use
Precision	Intra-run %CVs between 1% and 4%, between-day %CVs between 1% and 4%	Intra-run %CVs less than 2%, between-day %CVs between 3% and 4%

807.92 (b)(1): Brief Description of Nonclinical Data

Evaluations were performed for analytical sensitivity, within-assay precision, between-assay precision, linearity, sample stability, and interfering substances. Those resulting data are summarized below.

To determine the analytical sensitivity, twenty-one replicates of a saline reagent blank were analyzed as unknowns in one assay run. The analytical sensitivity is estimated to be 0.2 µg/ml, and this is defined as the mean 15AG concentration plus one standard deviation.

Within-assay precision, when evaluated at two levels of 15AG (low- 4.6 µg/mL) and high- 14.7 µg/mL), ranged from 1.28 %CV to 3.83 %CV. Between assay precision, when evaluated with two control samples and two serum pool samples (concentrations from 4.7 µg/mL to 27.0 µg/mL) ranged from 0.79 %CV to 3.71 %CV.

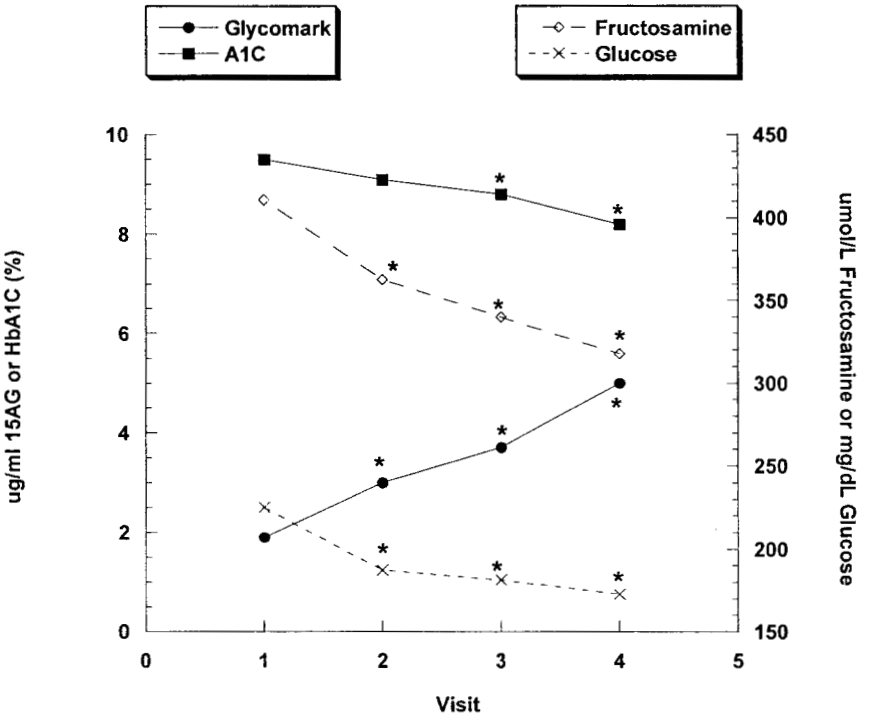
Results from linearity studies demonstrated that the GlycoMark™ test is linear up to at least 110 µg/mL 15AG. Results from sample stability studies demonstrated that serum samples may be stored at room temperature or at 2-8° C for up to seven days prior to analysis, and may endure up to three freeze/thaw cycles prior to analysis.

Results from interference testing showed that the GlycoMark™ test is not affected by hemoglobin up to 125 mg/dL (in the case of hemolyzed samples), triglycerides up to 1153 mg/dL (in the case of lipemic samples), and bilirubin up to 53.3 mg/dL (in the case of icteric samples).

807.92 (b)(2): Brief Description of Clinical Data

A prospective, longitudinal study was performed with 77 patients with diabetes (both type 1 and type 2). The patients exhibited suboptimal glycemic control (A1C level greater than or equal to 7%) at study entry, and these patients were monitored for eight weeks following initiation or modification of anti-hyperglycemic treatments. Measurements for GlycoMark, A1C, fructosamine, and glucose were performed every two weeks for the first four weeks (Visits 1-3) and then at Week 8 (Visit 4).

The figure presents the mean values for each marker by visit. An asterisk (*) denotes significant changes vs. baseline values ($p<0.05$, Wilcoxon signed-rank test). Significant changes vs. baseline appeared at Visit 2 for GlycoMark™, fructosamine, and glucose; whereas a significant change did not appear until Visit 3 for A1C.



807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the GlycoMark™ assay. The assay was shown to be safe and effective for its intended use, and was substantially equivalent to other intermediate and long term markers of glycemia.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 2 2003

Ms. Erika B. Ammirati RAC, MT(ASCP)
Regulatory Consultant
Tomen America, Inc.
1285 Avenue of the Americas
New York, NY 10019-6028

Re: k031604
Trade/Device Name: GlycoMark™
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: NOZ; JIS; JJX
Dated: August 29, 2003
Received: September 2, 2003

Dear Ms. Ammirati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K031604

Device Name: GlycoMark™

Indications for Use:
The GlycoMark™ test provides quantitative measurement of 1,5-anhydroglucitol (15AG) in serum or plasma. The test is for professional use, and is indicated for the intermediate term monitoring of glycemic control in people with diabetes.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031604